**R.T. Vanderbilt Company, Inc.**
INDUSTRIAL MINERALS AND CHEMICALS

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February 14, 2000

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket number 99D-4487

To Whom It May Concern:

Since the 1940's, the R. T. Vanderbilt Company, Inc. has manufactured chemicals for the rubber industry. These products include accelerators, retarders, antioxidants and antiozonants. Our extensive history in this field and ongoing research efforts have provided us broad expertise in the field of rubber chemistry. It is based on this knowledge that we offer comments on the Administration's draft "Guidance For Conducting Stability Testing To Support An Expiration Date Labeling Claim For Medical Gloves".

## I. The Administration Should Require Expiration Dating

We agree with and support the Administration's conclusion that the effectiveness of any biological barrier depends on its structural and, therefore, functional integrity. Because rubber products are subject to a variety of chemical and physical changes during storage, they should be tested to ensure their continued suitability for their intended purpose and we encourage the adoption of a standardized protocol to do this.

## II. To Achieve Its Desired Result, The Administration's Accelerated Aging Test Protocol Must Be Made More Severe

We agree with the Administration's conclusion that real-time stability data are the most reliable; however, real-time data can only be generated from real-time exposure. The Administration has addressed this by developing a protocol for an accelerated aging test.

We have conducted accelerated aging experiments using natural rubber gloves and glove materials. Many of our data were generated using thinly cast films which display an excellent correlation to dipped medical gloves. We have also tested finished gloves representative of industry standard products. Based on these data, we have reached the following conclusions.

A. As proposed, the accelerated aging test is not stringent enough for non-chlorinated gloves

The term "non-chlorinated gloves", at present, is almost synonymous with powdered gloves. Many natural rubber articles intended for skin contact are treated with a chlorinating agent (usually aqueous hypochlorite) to facilitate donning. Chlorination also reduces the amount of protein allergens on the surface of the article or, because of the oxidation, reduces the allergenicity of these proteins. By eliminating the need for donning powder (such as cornstarch), chlorination reduces the amount of allergen transferred from the glove to the skin and made airborne as well. Because there is no dust, chlorinated (dustless) gloves have become the glove of choice in medical applications.

We support efforts to reduce or eliminate powder, including chlorination. However, our preliminary data show that chlorinated gloves subjected to the accelerated aging test as proposed show significant deterioration in physical properties, approaching the limits set forth in ASTM D 573 (Figure 1). Our studies also show that the physical properties of non-chlorinated gloves are virtually unaffected by the proposed test conditions; in fact, the physical properties of non-chlorinated gloves are enhanced under these conditions (Figure 2). This is not unusual. Rubber goods manufacturers routinely vulcanize articles to only 90% of their maximum cure state. Heating articles to 70° C for seven days is so mild that it is merely an extension of the cure; this is known in the industry as a post cure. The improvement in physical properties found after aging at 70° C for seven days is the result of this post cure and is unaffected by a variety of modifications to the formulation.

Using the proposed accelerated aging protocol, we believe that only chlorinated gloves can fail and that all (or nearly all) non-chlorinated gloves will pass and have a two-year expiration date.

B. The Protocol Must Be More Stringent To Identify Superior Gloves

ASTM D 573 notes that a 10° C increase in the test temperature doubles the oxidation rate. However, ASTM D-1349 recommends increasing temperature in fifteen-degree increments, to 85° and then 100° C. To determine test conditions which will identify inferior gloves, we conducted preliminary studies at 100° C for 24 and 48 hours. Chlorinated and non-chlorinated gloves were tested at 100° C for 24 hours. Using this protocol, chlorinated (powderless) gloves decomposed (Figure 1) while non-chlorinated gloves retained approximately 83% of their original tensile strength (Figure 2). Although the number of gloves tested was too small for reliable statistical analysis, we believe that 85° C is a more appropriate test temperature for non-chlorinated gloves.

C. Even If The Protocol Is Revised To Make Test Conditions More Severe, It Is Possible To Make A Chlorinated Glove Which Will Pass The Test.

In another study using thin films made in our laboratory, we determined the effect of an antioxidant (Figure 3). Thin films of natural rubber with and without an amine antioxidant were prepared. One set of films was subjected to the accelerated aging test as proposed; the other was exposed to 100° C for 24 hours. The physical properties of an untreated rubber film were no different than one treated with an amine antioxidant. However, when films were exposed to 100° C for 24 hours, the difference between the films with and without the antioxidant became obvious. This means that the lower temperature test (70°) is not severe enough and, therefore, the results are meaningless.

III. Other Considerations

While we feel that the ASTM D 573 standard is very lenient (56.6 and 55.6% reduction in tensile strength and elongation, respectively) regarding natural rubber products, we cannot object to it in view of the preceding. However, we must call attention to the fact that the standard was written for dry rubber products. Dry rubber, because of processing, does not possess the inherently high physical properties of rubber deposited from latex.

We question the use of a "percent decrease in physical properties" as a measure for assigning an expiration date for two reasons. First: as written, this is a pass/fail test. If a batch of articles passes ASTM D 573, the expiration data is two years from date of manufacture. If the batch of articles fails ASTM D 573, there appears to be no consideration for what the expiration date of this batch will be. Second: this measurement can be manipulated. The properties of undercured products can actually increase during the test as proposed.

We favor a definitive measurement as used in the Standard Malaysian Glove Scheme; for example, 21 MPa minimum original tensile strength and 16 MPa minimum tensile strength after accelerated aging. We have yet to form an opinion on the exact value thresholds but we believe that using absolute versus relative (per cent change) data seems more appropriate and expeditious. For spot checking, it will not be necessary to assess the original properties to determine the expiration date.

As proposed, the result of the accelerated aging test is pass or fail; a glove which retains 57% of its original tensile strength passes while one which retains 56% fails. If the Administration remains committed to measuring decrease in physical properties, the use of the Arrhenius equation to determine expiration dates should be considered. By measuring change (in this case, decrease) in physical properties per unit time, the data can be extrapolated to the pre-defined failure point. This would allow manufacturers to determine the expiration date on individual lots of gloves based on the <u>rate</u> of deterioration rather than the degree of deterioration.

We are also concerned that any expiration dating, regardless of the method used to determine the expiration date, will persuade or even force manufacturers to abandon chlorination. Given the benefits of chlorination, we believe this would be a step backwards. Our preliminary studies show that chlorinated gloves will have difficulty passing the accelerated aging requirements for the maximum expiration date of 2 years from date of manufacture. It is for this very reason we conducted experiments to determine how to make a chlorinated glove that would have a two-year expiration date.

## IV. Conclusions

Since all natural rubber gloves, with or without antioxidant, will pass the proposed test, we believe there is no incentive for a manufacturer to advance his or her own glove technology to produce superior products for the benefit of the consumer.

Much of our testing was done at 100° C. Our data indicate that 100° C is too severe for this testing; chlorinated gloves did not fare well at this temperature, even when tested for only 24 hours. Eighty-five degrees C is the next recommended level above 70° C for testing in ASTM D 1349. We believe this is an appropriate test temperature for non-chlorinated gloves but we recommend additional studies.

We also believe that some chlorinated gloves will not pass the accelerated aging requirements for the maximum expiration date of two years from the date of manufacture. Our research shows that with the use of selective antioxidants and synergists, physical property requirements (ASTM D 573) can be satisfied at higher test temperatures required to distinguish inferior gloves over a two-year life span. We do not want manufacturers to abandon chlorination as a result of this proposed standard.

We also ask the Administration to extend the time for responses to this Draft Guidance by six months. This additional time will allow us and the glove manufacturers to perform enough testing on a statistically valid number of samples to evaluate our proposed revisions to the accelerated aging protocol.

It is not our intent to make life difficult for glove manufacturers; however, we believe that responsible manufacturers can offer the consumer quality products and should not be discouraged from doing so.

If you have any questions or need additional information, you may reach me by phone, facsimile or e-mail; my contact information is below.

Sincerely,

R. T. VANDERBILT COMPANY, INC.

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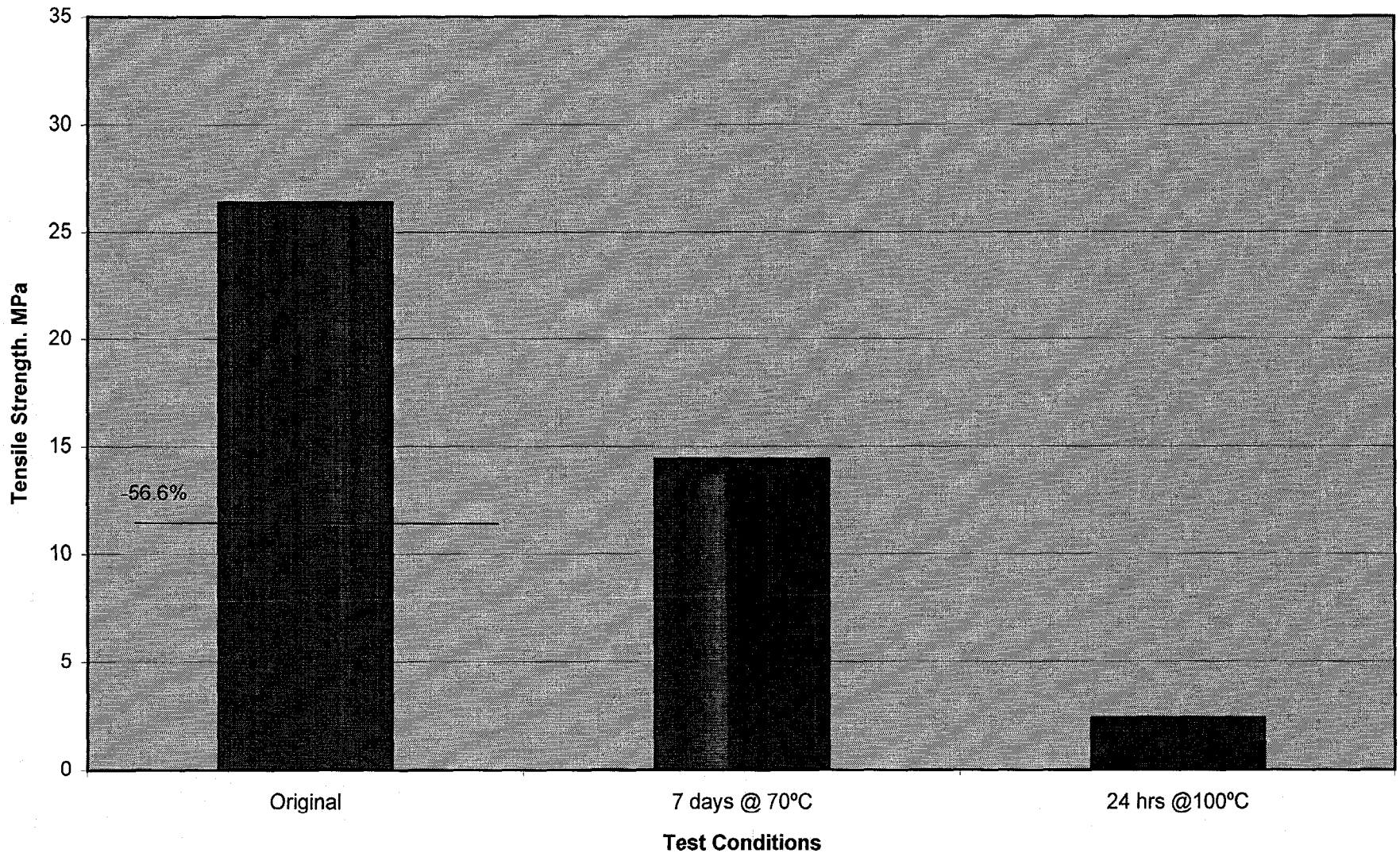
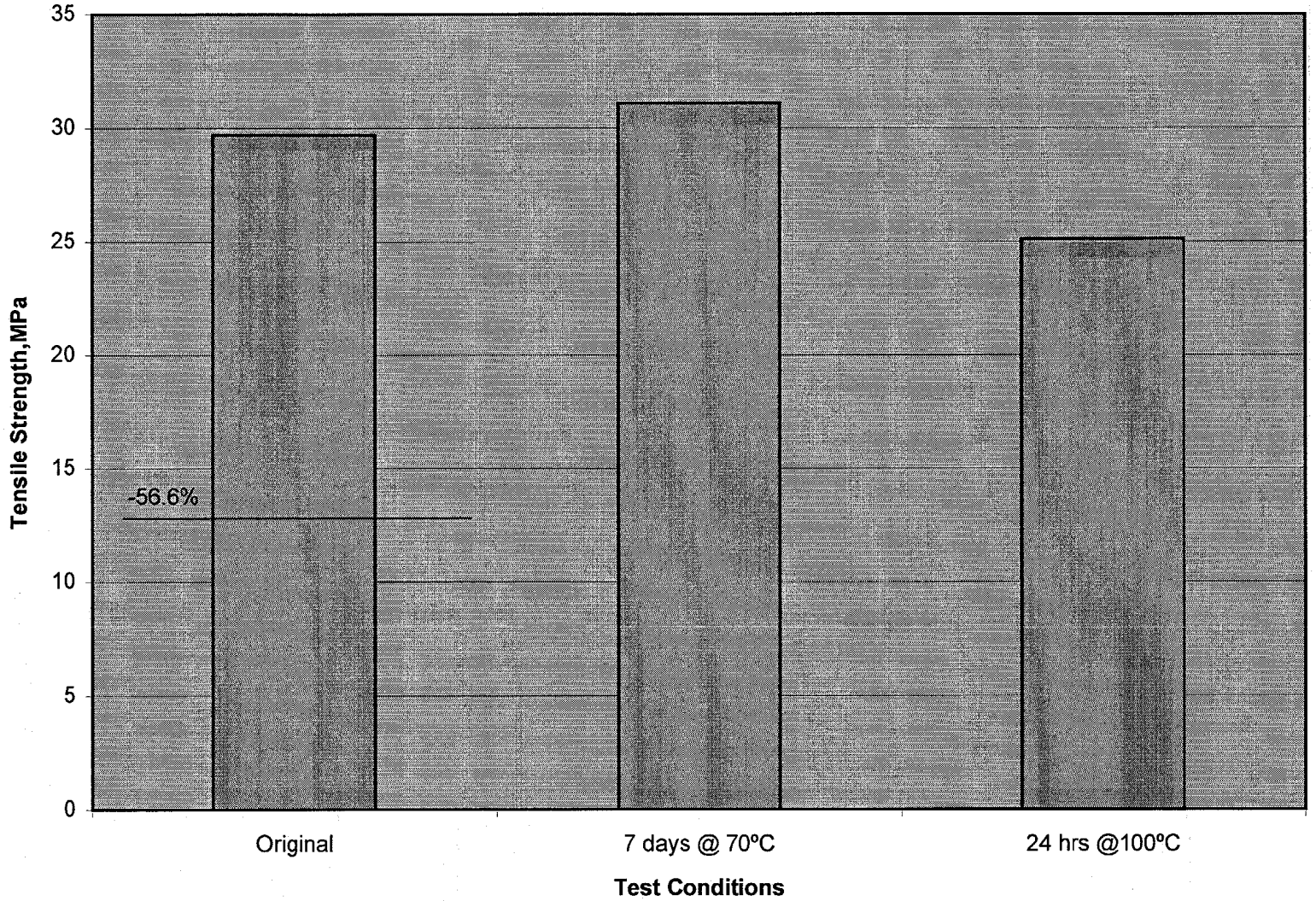
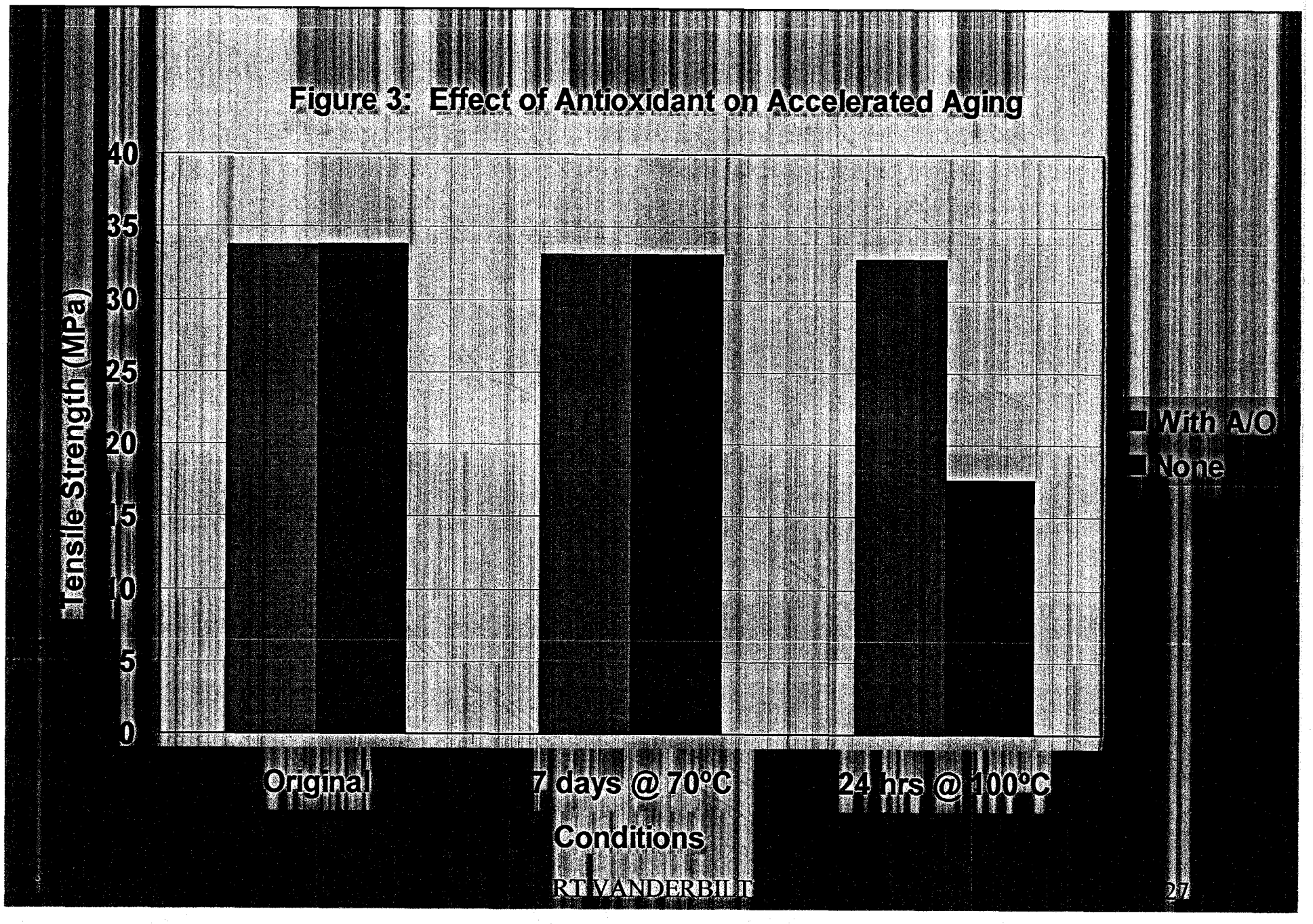
**Figure 1: Accelerated Aging of Chlorinated Gloves**



## Figure 2: Accelerated Aging of Non-Chlorinated Gloves



## Figure 3: Effect of Antioxidant on Accelerated Aging



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